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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,689	04/15/2005	Takashi Kenmoku	03500.017653	1818

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
LILLING, HERBERT J	
ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,689	KENMOKU ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of four prior art information disclosure statements filed April 15, 2005, August 12, 2005, October 18, 2005 and May 11, 2006.

2. Claims 1-29 are pending in this application which is a 371 of PCT/JP03/13531 filed October 23, 2003 which claims benefit to Japan 2002-310250 filed October 24, 2002 and Japan 2003-356748 filed October 16, 2003.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups I, claims 1-3, drawn to a FIRST PRODUCT of a polyhydroxy alkanoate copolymer characterized in including at least a 3-hydroxy-.omega. -alkenoic acid unit represented by a chemical **formula (1)** in a molecule,

and simultaneously at least

a 3-hydroxy-.omega.-alkanoic acid unit represented by a **chemical formula (2)**

or a

3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a **chemical formula** (3) in the molecule:
[Chemical Formula (1)] in which n represents an integer selected within a range indicated in the chemical formula; and in case plural units are present, n is the same or different for each unit as noted by Claim 1.

Whereby Claim 2
Indicated wherein R in the chemical formula (2) represents a residue having a phenyl structure or a thienyl structure selected from the group consisting of chemical formulas (8), (9), (10), (11), (12), (13), (14), (15), (16), (17) and (18): the chemical formula (8): represents a group of non-substituted or substituted phenyl groups

Group II, claims 4–6, drawn to SECOND **PRODUCT** of a polyhydroxy alkanoate copolymer characterized in including at least a 3-hydroxy-.omega. -carboxyalkanoic acid unit represented by a chemical formula (19) or 3-hydroxy-.omega. -alkoxycarbonylalkanoic acid unit represented by a chemical formula (32) in a molecule, and simultaneously at least a 3-hydroxy-.omega. -alkanoic acid unit represented by a chemical formula (2) or a 3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a chemical formula (3) in the molecule, [Chemical Formula (19)] in which n represents an integer selected within a range indicated in the chemical formula; R.sub.18 represents an H atom, a Na atom or a K atom: and in case plural units are present, n and R.sub.18 may be the same or different for each unit; and [Chemical Formula (32)].

Group III, claims 7, drawn to a **FIRST METHOD** for producing a polyhydroxy alkanoate copolymer characterized in including **a biosynthesis by a microorganism** having an ability of producing a polyhydroxy alkanoate copolymer including at least a 3-hydroxy-.omega. -alkenoic acid unit represented by a chemical formula (1) in a molecule, and simultaneously at least a 3-hydroxy-.omega.-alkanoic acid unit represented by a chemical formula (2) or a 3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a chemical formula (3) in the molecule, **from at least** an. omega.-alkenoic acid represented by a chemical formula (24) and at least a compound represented by a chemical formula (25) or at least an .omega.-cyclohexylalkanoic acid represented by a chemical formula (26) as starting materials.

Group IV, claims 14-20 drawn to a **SECOND METHOD** for producing a **DIFFERENT** polyhydroxy alkanoate copolymer including at least a 3-hydroxy-.omega.-carboxyalkanoic acid unit represented by a chemical formula (19) in a molecule, and simultaneously at least a 3-hydroxy-.omega.-alkanoic acid unit represented by a chemical formula (2) or a 3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a chemical formula (3) in the molecule comprising the steps of: preparing a polyhydroxy alkanoate copolymer including at least a 3-hydroxy-.omega.-alkenoic acid unit represented by a chemical formula (1) in a molecule, and simultaneously at least a 3-hydroxy-.omega.-alkanoic acid unit represented by a chemical formula (2) or a 3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a chemical formula (3) in the molecule as a starting material, and oxidizing a double bond portion in the polyhydroxy alkanoate represented in the chemical formula (1) thereby generating a polyhydroxy alkanoate copolymer including **at least a 3-hydroxy-.omega.-carboxyalkanoic acid unit represented by a chemical formula (19)** in a molecule, and simultaneously at least a 3-hydroxy-.omega.-alkanoic acid unit represented by a chemical formula (2) or a 3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a chemical formula (3) in the molecule.

Group V, claims 21-27, drawn to a **THIRD METHOD** for producing a different polyhydroxy alkanoate copolymer including a biosynthesis by a microorganism having an ability of producing a polyhydroxy alkanoate copolymer including at least a 3-hydroxy-.omega.-alkoxycarbonylalkanoic acid unit represented by a chemical formula (32) in a molecule, and simultaneously at least a 3-hydroxy-.omega.-alkanoic acid unit represented by a chemical formula (2) or a 3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a chemical formula (3) in **the molecule, from a dicarboxylic acid monoester compound represented by a chemical formula (42).**

Group VI, claims 28-29, drawn to a FOURTH METHOD for producing a polyhydroxy alkanoate copolymer, characterized in employing a polyhydroxy alkanoate copolymer including at least a 3-hydroxy-.omega.-alkoxycarbonylalkanoic acid unit represented by a chemical formula (32) in a molecule, and simultaneously at least a 3-hydroxy-.omega.-alkanoic acid unit represented by a chemical formula (2) or a 3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a chemical formula (3) in the molecule as a starting material, and executing a hydrolysis in the presence of an acid or an alkali or executing a hydrogenolysis including a catalytic reduction, thereby generating a polyhydroxy alkanoate copolymer including at least a 3-hydroxy-.omega.-carboxyalkanoic acid unit represented by a chemical formula (19) in a molecule, and simultaneously at least a 3-hydroxy-.omega.-alkanoic acid unit represented by a chemical formula (2) or a 3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a chemical formula (3) in the molecule,

The above inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1 as drawn to different products as well as different methods of preparing the products.

4. This application contains claims directed to the following patentably distinct species:

A. Whereby the polyhydroxy alkanoate copolymer characterized in including at least a 3-hydroxy-.omega. -alkenoic acid unit represented by a chemical formula :

w. 1;

x. 19;

y. 32;

z. other – please specify.

B. Whereby the polyhydroxy alkanoate copolymer characterized in including at least a 3-hydroxy-.omega.-alkenoic acid unit represented by a chemical formula (1), (19) , (32) or other –please specify in a molecule, and simultaneously at least with :

a. 3-hydroxy-.omega.-alkanoic acid unit represented by a chemical formula (2)

b. 3-hydroxy-.omega.-cyclohexylalkanoic acid unit represented by a chemical formula (3) in the molecule

c. mixture of the above.

C. Whereby the polyhydroxy alkanoate copolymer represents a residue having :

i. phenyl structure;

selected from chemical formulas:

a. 8,

b. 9,

c. 10,

d. 18

e. other(s) specify.

ii. thienyl structure.

Selected from the chemical formulas:

1. 11,
2. 12,
3. 13,
4. 14,
5. 15,
6. 16,
7. 17,
8. other(s) specify.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) elections of a species as noted by A, B and C and an invention I-V to be examined even though the requirement be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. In accordance with this Tech Center Policy, rejoinder of non-elected claims will be governed by the decisions as noted by the following paragraphs:

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See

"Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. In addition, the following paragraphs will probably be required by Applicant to be in full compliance with respect to any possible rejection(s) based on the specific strains:

U.S. Patent Rules of Deposits

It is apparent that the strain(s) is (are) required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strain(s). See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining the strain(s) and it does not appear to be a readily available material. Deposit of the strain(s) would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material **will be irrevocably** removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function n the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

Please note that the mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available.

It is noted that the following strains will probably be required to be in compliance with US Rules of Deposit:

These four types of strains are deposited on Nov. 20, 2000 at International Patent Organism Depositary, National Institute of Bioscience and Human-Technology, Agency of Industry Science and Technology (independent administrative corporation), Tsukuba Central 6, 1-1, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken 305-8566, Japan, and described in the Japanese Patent Application Laid-Open No. 2002-80571.

Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

10. The exceptional very lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
Art Unit **1657**
June 09, 2007

Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657